PMDA Updates

2025 Summer

Index

Highlights

Why Japan Should Be on Your Map for Medical Innovation

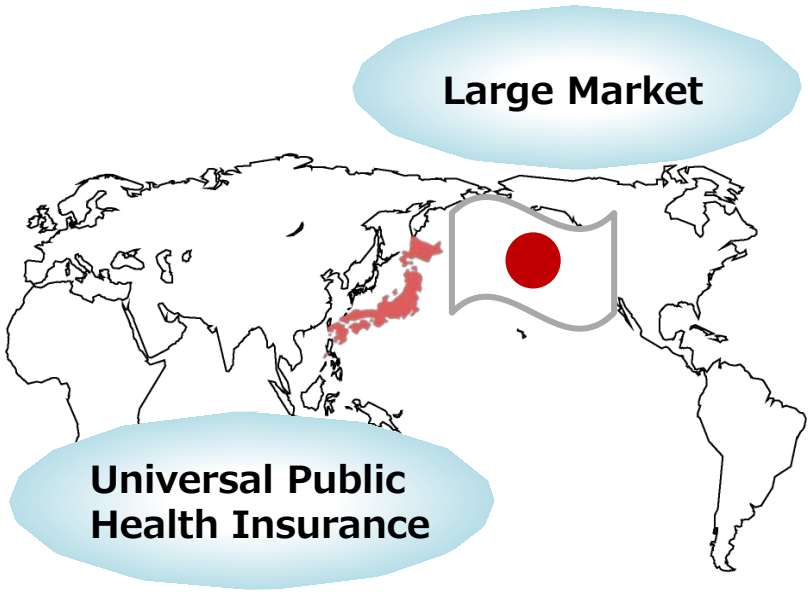
Japan has a variety of attractions such as rich nature, profound history and tradition, a variety of foods, and cutting-edge technologies. Also, the development of medical products is a field in which Japan is among the world leaders. We introduces the attractiveness of Japan to people who are interested in the development of medical products in Japan from three perspectives of market, development timeline, and convenient system and support for companies.

1. Attractive Japanese market

The Japanese market has three attractions.

1. **Pharmaceuticals: The 4th largest market in the world**[*1]
2. **Medical devices: The 4th largest market in the world**[*1]
3. **High medical access for patients**

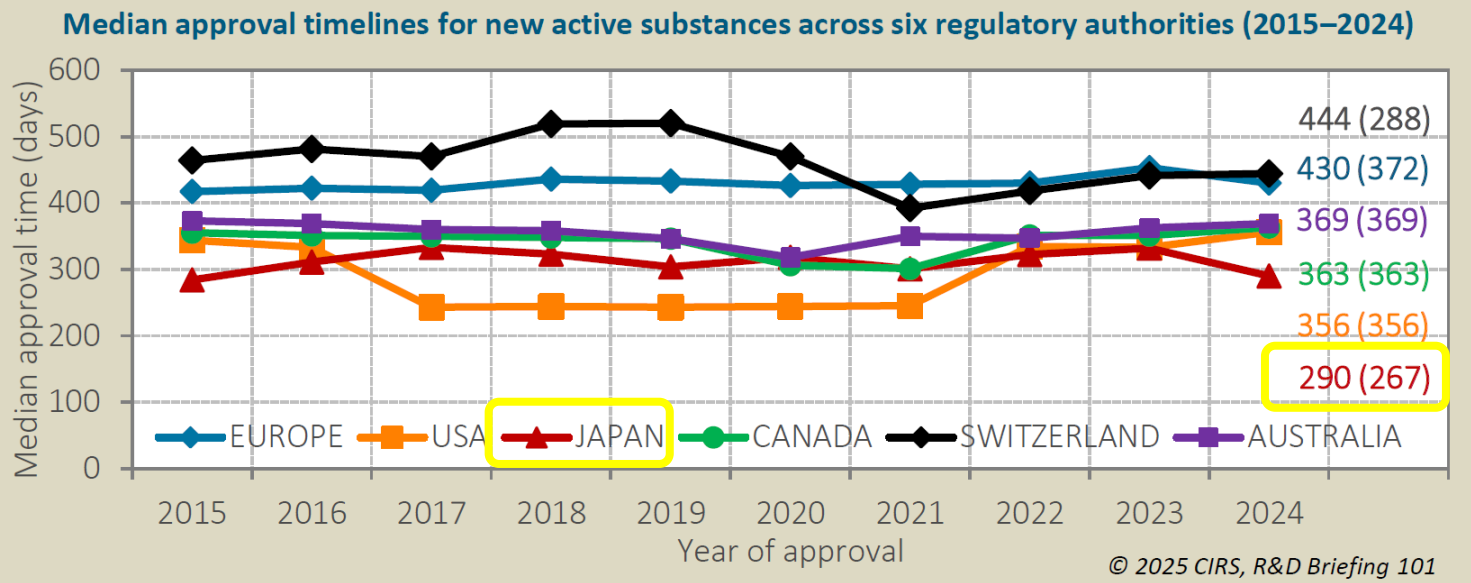
*1 Due to the weakening of the yen



As a background, all citizens take out public health insurance, and therefore, most medical expenses are covered by the public health insurance. In other words, the financial burden of patients is small and new medical products tend to readily spread. Since healthcare infrastructure is established, healthcare resources are distributed nationwide. As a result, medical access for patients is high, and the demand for medical products is stable. In Japan, the demand for medical products is expected to continuously increase as the population ages.

2. Easy to predict the timing of launch

In Japan, the review process for pharmaceuticals and the timeline for NHI price listing (determination of the public price for domestic uniformity) are highly transparent, and it is characteristically easy to predict the timing of launching a product to the market.



Approval time is calculated from the date of submission to the date of approval by the agency. This time includes agency and company time. EMA approval time includes the EU Commission time. N1 = median approval time for products approved in 2024; (N2) = median time from submission to the end of scientific assessment for products approved in 2024.

Speedy Review!

The standard total review time from new drug application to approval is 9 months for priority review products and 12 months for standard items, and the achievement rate was 80% or higher in FY 2023. The review time for new drugs is at the world's top level, comparable to that in Europe and the US (Figure above).

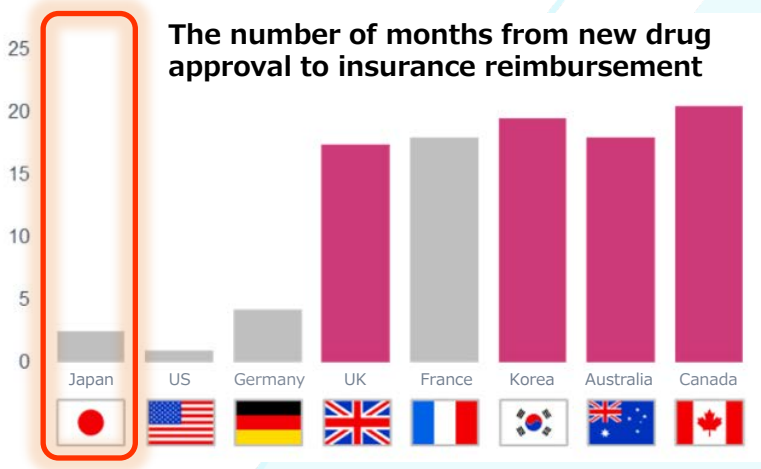
Globally Harmonized Regulations

PMDA participates in the International Council for Harmonisation of Technical Requirements for Pharmaceuticals for Human Use (ICH) as a founding member.

In the development and revision of pharmaceutical guidelines, we dispatch many experts to lead consensus building with the US and Europe. Therefore, it is easy to foresee regulatory compliance and control the unexpected investment risks.

Rapid, Predictable Launch

The period from the approval of a new drug to the listing in the NHI (determination of the public price for domestic uniformity) is within 60 days in principle or within 90 days at the latest. In addition to a very short period compared to other countries (Figure below), it is easy to forecast the timing of the launch.



Source (in Japanese): https://www.phrma-jp.org/hta/

: Countries that do not use cost-effectiveness analysis to determine whether or not insurance coverage is available

: Countries that use cost-effectiveness analysis to determine whether insurance coverage is available

3. Priority review system

The speed of new drug reviews has been increasing in Japan in recent years. In particular, special measures such as the "SAKIGAKE Designation System" are taken for innovative medical products. In addition, a system for priority review has been introduced.

For example, we have “orphan drugs designation system" and "conditional approval system," and by using them, the standard review time of 12 months will be shortened to 9 months*2.

By receiving the designation and using these systems, companies developing medical products can enter the market more rapidly in Japan.

*2 For orphan drugs, only those determined to be eligible for priority review

See the details here.
Why Japan for drug development Vol.1 (presentation for ENDPOINTS Events)

The details of the information are provided on the information collection page of the PMDA website. If you are interested, please visit the site.

For Industry - for development in Japan

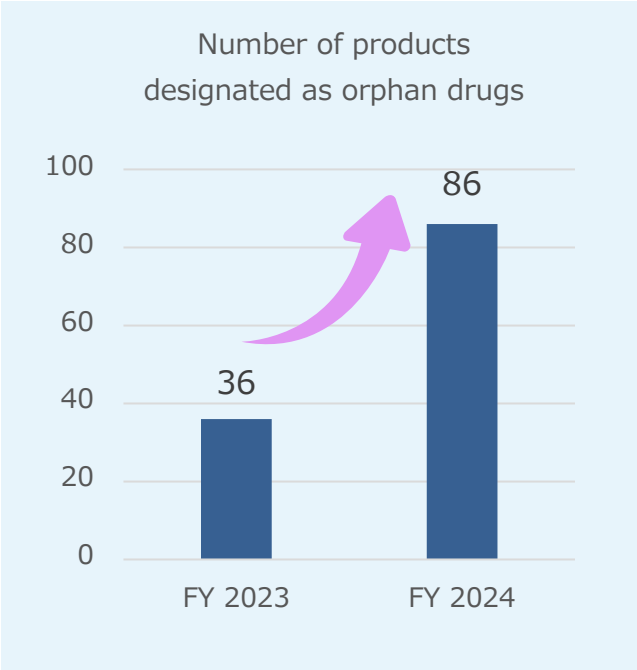
4. Support for companies that implement development in Japan

RS consultation

PMDA conducts Regulatory Science (RS) consultations (RS general consultations and RS strategy consultations) on study plans, etc. from the final stage of selection of candidates for development to the initial stage of clinical development for start-ups/venture companies and academia. We have started general consultations on pharmaceutical affairs (free of charge) for US-based companies at our Washington D.C. office during US business hours (see page 10).

Designation of orphan drugs

The designation criteria were revised in 2024 so that orphan drugs, can be designated at an earlier stage of development and the number of designated products has been greatly increasing. For the development of pharmaceuticals designated as orphan drugs, the institution which promotes the development of pharmaceuticals, etc. (National Institutes of Biomedical Innovation, Health and Nutrition [NIBN]) gives a grant and also preferential tax treatment can be used. In recent years, Japan Agency for Medical Research and Development (AMED), a research funding agency, has been conducting a grant project for products aimed at designation as orphan drugs.



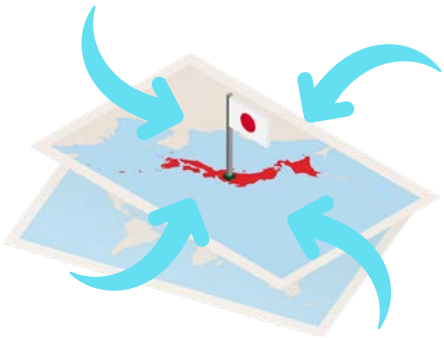
News

Challenge to creating an appealing clinical trial environment

Toward the introduction of the clinical trial ecosystem to efficiently conduct clinical trials through the cooperation of all stakeholders

PMDA started a new activity (Clinical Trial Ecosystem Introduction Promotion Project) to improve the efficiency of clinical trials in cooperation with Ministry of Health, Labour and Welfare (MHLW) and medical institutions in 2024. We will create an environment where clinical trials can be easily conducted by reducing costs and eliminating the burden of procedures through this project.

The project was led by medical institutions. In the first year, they tried to find issues, and the following three issues were identified.



Three issues to be solved that have been identified in this project

Regulation

The IRB[*1] review in Japan is currently being conducted by the IRB of each medical institution in many cases, even for multicenter trials, and a lot of time has been spent on handling it. Through this project, we confirmed that both the medical institutions and the sponsors were positive about the introduction of Single IRB[*2].

*1 Institutional Review Board

*2 Review by a single institutional review board for a multicenter trial

Quality of clinical trial

It is said that one monitor is responsible only for a small number of trial sites and the trial costs are high in Japan. One of the reasons is "over quality," or seeking quality of trial too much. Through this project, we confirmed that this issue was mostly caused not by regulations but by the operational aspect.

Standardization of format

There are unified forms for materials necessary for IRB review in Japan, and their use has been widely spreading. In addition to them, we have identified materials whose formats can be further standardized such as Delegation log[*3].

*3 Documents prepared to clarify the division of tasks in clinical trials

By solving these three issues, it is expected to shorten the time to start a clinical trial and reduce clinical trial costs without compromising the quality. Particularly, regarding the issue with the regulatory framework, the revision of GCP[*4] ministerial ordinance is now being examined, and we are carrying forward a comprehensive review along with this revision.

*4 Good Clinical Practice

We expect that the clinical trial environment will be improved from both aspects of regulation and operation and clinical trials conducted in Japan will be carried forward more efficiently. This project is continuing this fiscal year, and we are examining specific solutions to the issues identified in the previous fiscal year. Please keep focusing on the results.

Topics

Introduction of Early Consideration

What is Early Consideration?

It is the PMDA's view on the direction of development at the point when information, etc. have not been sufficiently accumulated.

Please check the details of the Early Consideration related to the development area and field on the PMDA website.

See the details here English

Early Consideration (1)

Points to Consider for Clinical Efficacy Evaluation of Drugs for Palmoplantar Pustulosis

Palmoplantar pustulosis (PPP) is a disease in which sterile pustules repeatedly appear on the palms and soles. Differences in the concept of the disease between Japan and overseas make it difficult to develop therapeutic drugs. At a symposium of the annual meeting of the Japan Society of Clinical Trials and Research in March 2024, discussions were held on drafting, implementation, and evaluation of clinical trials of therapeutic drugs for PPP. The summary is presented as a matter to be noted when planning a clinical trial of a new therapeutic drug for PPP.

See the details here English

Early Consideration (2)

Example of Documents on Assessment and Control of DNA Reactive (Mutagenic) Impurities attached to Clinical trial Notification

When a clinical trial notification is submitted, it is necessary to attach the contents showing that DNA reactive (mutagenic) impurities*1 have been evaluated and controlled from the development stage of pharmaceuticals according to the ICH M7 guideline, etc. to the clinical trial notification. In this Early Consideration, examples of descriptions of materials to be attached to clinical trial notifications and its checklist were presented. They are expected to improve the efficiency of investigations of clinical trial notifications and promote smooth implementation of clinical trials.

*1 Impurities capable of directly damaging DNA by chemical reaction with DNA

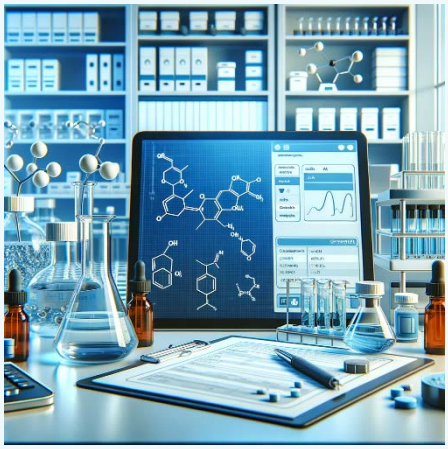
See the details here English

Early Consideration (3)

Checklist for Common Inquiry Cases to Be Noted When Submitting Approval Applications for New Active Ingredient Containing Pharmaceuticals (Chemical Products)

Documents and actions required for approval application of drugs with new active ingredients (chemical products) are shown in administrative documents, ICH guidelines, etc., but companies with little experience of approval application in particular can hardly predict what specific data and actions are required. For this reason, we prepared a checklist based on frequently inquired matters related to the quality of chemical products in the past, expecting that approval applications and reviews will be implemented faster and in a more transparent manner. Please refer to this checklist as appropriate considering the characteristics and status of the item.

See the details here English



This illustration was generated using OpenAI's ChatGPT

Early Consideration (4)

Points to Consider in Developing Drugs for Pediatric Inflammatory Bowel Disease

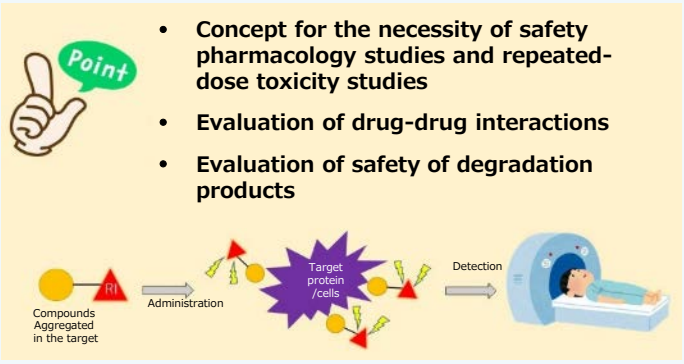
In recent years, pharmaceuticals for inflammatory bowel diseases (IBD) such as ulcerative colitis and Crohn's disease have been actively developed. In particular, for moderate to severe IBD, multiple drugs with different mechanisms of action have been approved such as biologics, Janus kinase inhibitors, and sphingosine 1-phosphate receptor modulators. However, most of them were approved based on the results of clinical studies in adult IBD patients, and the dosage and administration for pediatric patients have not been investigated. Therefore, in order to promote the development of drugs for pediatric IBD, we decided to publish points to be noted in this development in the form of "Early Consideration." These points to be noted will be disseminated to academic societies, etc. in the future.

See the details here English

Early Consideration (5)

Considerations for Non-Clinical Studies in the Development of Diagnostic Radiopharmaceuticals

The necessity of safety pharmacology studies and repeated-dose toxicity studies in the development of diagnostic radiopharmaceuticals is shown in the "Guidelines for Clinical Evaluation of Diagnostic Radiopharmaceuticals" issued in 2012. However, discussions frequently arise regarding the non-clinical study items, timing of their implementation, etc.



See the details here English

Therefore, in order to clarify the regulatory viewpoint, and to explain how to evaluate drug-drug interactions and the safety of degradation products in diagnostic radiopharmaceuticals based on the newly issued ICH guidelines, key considerations regarding non-clinical evaluation of diagnostic radiopharmaceuticals have been compiled.

Series

Do you know the easy-to-use consultation system for academia and start-ups/venture companies?

- Volume 2: Utilization of the Kansai Branch -

Nakanoshima Qross where the Kansai Branch has an office

PMDA provides "consultation services" to scientifically discuss and provide advice with developers on plans for nonclinical studies and clinical trials in the development stage as well as on other measures to ensure the quality of products.

As part of the services, PMDA has RS general consultations/strategy consultations as consultation services for academia and start-ups/venture companies with no development experience or inexperienced based on the PMD Act.

In this issue, we introduce the Kansai Branch where RS general consultations/strategy consultations are conducted in addition to the Tokyo Headquarters.

Kansai Branch

The Kansai Branch was established in October 2013 and moved to the current Nakanoshima Qross in December 2024.

Nakanoshima Qross is a base where medical institutions, corporations, start-ups and support organizations are located under the same roof. We expect that consultations from the early stage of development would be easier than before by establishing the base of the Kansai Branch of PMDA there. The Kansai Branch will participate in various gatherings so that their existence can be more visible.

RS consultations at Kansai Branch

There are staff members who specialize in pharmaceuticals, medical devices, and regenerative medical products at Kansai Branch. They provide RS general consultations and RS strategy consultations (pre-consultation meeting) in person or via web conference, or hybrid style, similarly to the Tokyo Headquarters. Also, RS strategy consultations are conducted by connecting a video conferencing system with the Tokyo Headquarters. The video conferencing system allows consultations involving participants from overseas by using a simultaneous interpretation system. Furthermore, RS general consultations and RS strategy consultations (pre-consultation meeting) by the staff members of the Kansai Branch are also available at the "PMDA Strategic Consultation and Cooperation Center" established in the "Foundation for Biomedical Research and Innovation at Kobe."

Operations at the Kansai Branch

The Kansai Branch implements the following two operations.

- RS general consultations/strategy consultations mainly for universities/research institutions and start-ups/venture companies located in the Kansai area
- Operations such as GMP inspections for manufacturing sites of pharmaceuticals, etc. mainly located in the Kansai Area and Asian Region

By connecting the video conferencing system, all consultations provided by PMDA can be conducted at the Kansai Branch.

Members of the Kansai Branch

In the next Autumn issue, we will introduce the **pre-consultation meeting**.

Activities of overseas offices

Part 1 General consultations at PMDA Washington D.C. office

Since March 2025, the PMDA Washington D.C. office has been conducting a general consultations on Japanese pharmaceutical regulations for US companies seeking to obtain regulatory approval in Japan. This section introduces the contents that can be consulted at the D.C. office and our efforts to make those consultations more meaningful opportunities.

What kinds of matters can be consulted on?

In the general consultation, the D.C. office provides the information on regulations, procedures, etc. related to the development of medical products in Japan to start-ups and venture companies developing pharmaceuticals, medical devices, and regenerative medical products in the US.

We have already received several requests for consultation regarding “the regulations and procedures based on the Pharmaceuticals and Medical Devices Act[*1]" and “PMDA's operations, type of consultation, and consultation procedures with the PMDA review team at the Tokyo Headquarters." We are responding to these requests in order.

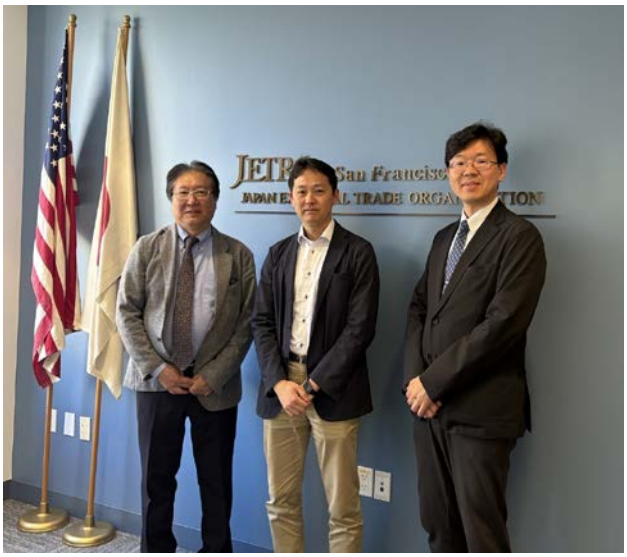
*1 Act on Securing Quality, Efficacy and Safety of Products Including Pharmaceuticals and Medical Devices (No. 145, 1960)

You can apply for general consultations on the website below. We welcome consultation requests from US companies seeking to obtain regulatory approval in Japan.

PMDA Washington D.C. Office
General Consultation Service

Entrance of PMDA Washington D.C. Office

To make consultations more meaningful opportunities



At JETRO San Francisco office

The PMDA Washington D.C. office is also working to build and strengthen networks with relevant organizations, including accelerators in the US that support the development of pharmaceuticals, medical devices and regenerative medical products.

This time, we would like to introduce one of those initiatives. The D.C. office is actively working to establish relationships with the Japan External Trade Organization (JETRO), which supports foreign companies investing and expanding their businesses for Japan. JETRO has six offices in the US, and we have so far visited the offices in New York and San Francisco to build relationships for promoting development of medical products in Japan. General consultations may include not only pharmaceutical regulations, but also the consultations on business deployment for starting development in Japan. In such cases, we will strive to provide as many useful opportunities as possible to promote business expansion in Japan by appropriately introducing relevant government agencies, such as JETRO offices in North America.

We will introduce the **activities of the PMDA Asia Office** in the next Autumn issue.

Upcoming Events

See you at the 22nd DIA Japan Annual Meeting 2025!

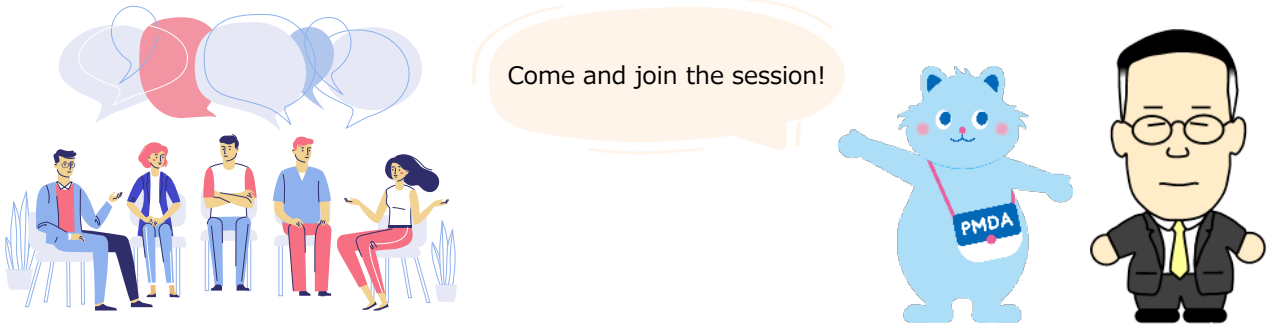
"The 22nd DIA Japan Annual Meeting 2025" (October 19-21, 2025 at Tokyo Big Sight) will be held under the theme of "Strong Ties of Japan with Asia and the World for Delivering 'Tomorrow's Normal' to Patients" with Dr. Yasuhiro Fujiwara, Chief Executive of PMDA, serving as Grand Chairperson, and Dr. Yoshiaki Uyama, Associate Executive Director of PMDA, serving as Vice Chairperson.

This year's meeting offers an opportunity for all local and global stakeholders who are considering the future of medical care to strengthen their partnerships, including cross-border cooperation, to promote innovation and advance medical care by sharing their knowledge and experiences.

Learn more from here
[The 22nd DIA Japan Annual Meeting 2025]

There will be special sessions with themes such as "development strategy of the US bio-venture companies and clue for the elimination of drug loss in Japan and Asia" and "Toward tomorrow's normal through AI ulitization" and also the sessions to discuss the development to be carried out in Asia from the patient's perspective and the developer's perspective. Also, we are planning to hold a public lecture on information literacy and host an exhibition booth of PMDA.

At this meeting, we will collaborate together to create "Tomorrow's Normal" in which everyone can feel peaceful and lead vibrant and healthy lives. PMDA would like to explain the latest efforts for reviews, safety, etc. and confirm the issues to be addressed by PMDA and the direction through discussions with relevant parties. We look forward to seeing you.



Information

International harmonization activities for pharmaceuticals and medical devices regulations

Report of the 7th Asian Network Meeting

What is the Asian Network Meeting (ANM)?

ANM is a meeting attended by high level representatives from regulatory authorities in Asian countries. It is held in Japan every year, and it was the 7th meeting this year from the 1st meeting in 2017.

We aim to adjust differences in regulations within the region and achieve harmonization and convergence by sharing efforts related to pharmaceutical regulations in Asian countries and exchanging opinions on common issues.

ANM is co-hosted by China, India, Japan (MHLW/PMDA), and Singapore, and in addition to these countries, Indonesia, Korea, Malaysia, the Philippines, and Thailand participated.

It is the only high-level meeting where regulatory authorities can discuss regulatory affairs in the Asia region. It plays an important role in strengthening cooperation with Asian countries.

7th Asian Network Meeting

Consensus on "promotion of clinical trials in the Asian region" and "proactive use of Reliance for prompt introduction of pharmaceuticals"

The 7th Asian Network Meeting was held in Tokyo on April 23.

In the morning session, each country made a presentation on the activities and progress of pharmaceutical regulations and deepened mutual understanding.

In the afternoon session, we exchanged specific opinions on the issues faced in the promotion of clinical trials, the measures for them, and best practices in each country toward the promotion of Reliance* for prompt introduction of pharmaceuticals. We strengthened the relationships between countries through close discussions for over 7 hours and agreed to promote further cooperation within the region.

*The regulatory authorities emphasize and consider the results of evaluation by other regulatory authorities in regulatory review and inspections and use them for the regulations in their own country.

See the meeting summary here English

Representatives from regulatory authorities visited Shonan iPark.

Introducing "Shonan iPark," Japan's leading open innovation base, to Asia

On the day following the ANM meeting (April 24), representatives from regulatory authorities visited Shonan iPark, Japan's representative open innovation base. In addition to a tour of the facilities, we had a panel discussion, where we listened to the actual voices of start-ups and drug discovery support companies that have their offices there and deepened the understanding of the roles of Shonan iPark.

Dr. Toshio Fujimoto, CEO of iPark Institute Co.,Ltd., the operating company of Shonan iPark, emphasized the attractiveness of the facilities to representatives of each country saying, "We hope to further expand our scale as an open global drug discovery innovation base."

Some participants from Asian countries said, "it looks attractive to various stakeholders as an open innovation base."

Report of the 2nd PMDA Reliance Meeting

Discussions towards swifter introduction of pharmaceuticals

The 2nd PMDA Reliance Meeting was held in Tokyo on April 21. Continuing from the previous year, leadership from Southeast Asia and WHO shared updates and discussed the promotion of Reliance schemes. Regulatory agencies from Brunei, Laos, Malaysia, the Philippines, Singapore and Thailand were represented.

The following was presented at the meeting:

- Facilitating Reliance, supporting ASEAN Joint Assessment (WHO)
- ASEAN Joint Assessment updates (JA Chair)
- Reliance Scheme for fast access to pharmaceutical products (Thailand and Singapore)
- PMDA's collaboration for fast access to pharmaceutical products (PMDA)

Round table discussion highlights:

- For regulatory harmonization, we confirmed that we would have continuous communication between ASEAN countries, promote mutual understanding of regulations in each country, share and implement best practices, use international guidelines, and improve assessment capability of personnel.
- It was important to continue awareness-raising activities toward the industry for promoting Reliance and also provide continuous and effective training using PMDA-ATC seminars for capability building.

To further strengthen cooperation!

The Food and Drug Administration of the Republic of the Philippines, the Ministry of Health, Labour and Welfare, and PMDA signed a Memorandum of Cooperation on medical products regulation dialogue and cooperation framework

On April 24, the Food and Drug Administration of the Republic of the Philippines (FDA Philippines), the MHLW, and PMDA signed a "Memorandum of Cooperation between the department of health and the Food and Drug Administration of the Republic of the Philippines and the Ministry of Health, Labour and Welfare and the Pharmaceuticals and Medical Devices Agency of Japan on medical products regulation dialogue and cooperation framework."

Main fields of future cooperation based on the memorandum

- Information exchange and cooperation on regulations of medical products
- Cooperation in the field of pharmaceuticals, biological products, and medical devices
- Scientific cooperation, training of human resources, cooperation in multinational forums

It is expected that this memorandum will promote further cooperation between the two countries.

The MHLW and PMDA will continue to work with the FDA Philippines on international regulatory harmonization activities to strengthen cooperation based on the trust between the two countries.

Memorandum of Cooperation

PMDA-ATC online at your fingertips!

PMDA Asia Training Center for pharmaceuticals and medical devices regulatory affairs

PMDA-ATC:

Asia Training Center for Pharmaceuticals and Medical Devices Regulatory Affairs

Two types of English videos are provided for overseas

Learning Video (Pmda Channel/YouTube)

Videos for the general public, introducing pharmaceutical regulations. About 50 videos available, listed by category, such as pharmaceuticals and medical devices.
Bioequivalence study is particularly popular, recording 10K+ views.

Access from PMDA-ATC website!

For regulators

E-Learning Course (Platform, registered access)

Videos for overseas regulatory authorities with more specialized and specific examples on pharmaceuticals reviews.
For example, PMDA review cases for cellular and tissue-based products and gene therapy products, responding to high demand.
With registration, one can access 60 videos comprising 4 courses in pharmaceuticals, advanced therapy medicinal products, herbal medicines, and medical devices.
Registration and access is free of charge.

Register here

Pharmaceuticals Review Webinar applications open soon

Applications to participate will open in September. Lectures will cover regulatory review in Japan, bioequivalence studies, ICH M13 guideline, and evaluations of generic drugs. Specific examples and methods of bioequivalence studies from PMDA review experience will be shared in detail, responding to high demand.

Dates: December 9-11, 2025
Format: Online
Audience: Regulators

Past participants' comments
"It was a very instructive seminar. I think I can use what I learned for my daily work."
"It was a good seminar. I learned a lot."

Seminar details are posted 3 months prior on the PMDA website. Seminar Schedule.

The seminar report is posted.

More information available from links, participants' comments included.

Seminars
Pharmacovigilance Seminar 2025 (February 2025)
Safety Reporting System of Clinical Trial Webinar 2025 for NPRA, Malaysia (April 2025)
Medical Devices Regulatory Seminar 2025 for AMDC, in Jakarta, Indonesia (May 2025)
SaMD Webinar 2025 for Thai FDA, Thailand (May 2025)
Pediatric Review Seminar 2025 (June 2025)
Over-The Counter (OTC) Drugs Seminar 2025 for NPRA, Malaysia (June 2025)

Through ATC initiatives, PMDA will further promote regulatory harmonization and elevate regulation standards across Asia and other regions, thereby strengthening mutual cooperation.

English Translations of Review Reports

The following links provide the latest information on the English versions of the review reports on the PMDA website:

Drugs Review Reports: Drugs

Brand Name	Non-Proprietary Name	Indication	Posting Date (Approval Date)
Kisunla Intravenous Infusion 350 mg	Donanemab (Genetical Recombination)*	Slowing the progression of mild cognitive impairment and mild dementia due to Alzheimer's disease.	May 27, 2025 (September 24, 2023)
Fabhalta Capsules 200 mg	Iptacopan Hydrochloride Hydrate*	Paroxysmal nocturnal haemoglobinuria	June 18, 2025 (June 24, 2024)
LivtencityTablets 200 mg	Maribavir*	Cytomegalovirus disease in organ transplantation (including hematopoietic stem cell transplantation) that is refractory to conventional anti-cytomegalovirus therapy.	July 3, 2025 (June 24, 2024)
Tepoxx Capsules 200 mg	Tecovirimat Hydrate*	Smallpox, mpox, cowpox, as well as complications due to replication of vaccinia virus following vaccination against smallpox.	July 10, 2025 (December 27, 2024)
Covgoze Intramuscular Injection	Recombinant Coronavirus (SARS-CoV-2) Vaccine	Prevention of disease caused by SARS-CoV-2 infection (COVID-19)	July 10, 2025 (June 24, 2024)
Ryjusea Mini Ophthalmic Solution 0.025%	Atropine Sulfate Hydrate*	Slowing the progression of myopia	July 22, 2025 (December 27, 2024)

*Japanese Accepted Name (modified INN)

English Translations of Notifications and Administrative Notices

We introduce the latest information on the English versions the notifications and administrative notices published on the PMDA website.

Document Type & No.	Title	Summary	Posting Date (Issue Date)
PSEHB/MDED Notification No. 0831 (2) August 31, 2020	Handling of the Conditional Approval of Medical Devices and In Vitro Diagnostic Pharmaceuticals EN/JP	For innovative medical devices for diseases that have a significant influence on life and no existing effective treatments, there will be great difficulty in collecting the clinical data necessary for approval applications for reasons such as the prolongation of clinical development due to the small number of patients and considerable time required for the implementation of clinical trials. For these reasons, based on "Conditional Early Approval System for Innovative Medical Device Products (Fast-Break Scheme)" (PSEHB/MDED Notification No. 0731-1, issued by the Director of the Pharmaceutical Safety and Environmental Health Bureau, Ministry of Health, Labour and Welfare (hereinafter referred to as "MHLW"), dated July 31, 2017) (hereinafter referred to as the "previous notification"), we have been planning post-marketing risk management from the development stage, including setting of conditions for use and post-marketing data collection, and promoting early practical use of medical devices with a balance between risks and benefits, on the premise that we will take strict measures against risks that will not be revealed by limited clinical data obtained before application. We have now clarified this legally as a system under the Act on Securing Quality, Efficacy, and Safety of Products Including Pharmaceuticals and Medical Devices (Act No. 145 of 1960) as amended by the Act for Partial Amendment of the Act on Securing Quality, Efficacy, and Safety of Products Including Pharmaceuticals and Medical Devices (Act No. 63 of 2019), which approves Article 23-2-5, Paragraph 1 or Paragraph 15 of the Act with conditions pursuant to the provisions of Paragraph 12 of the same Article, and the handling of this law has been stipulated in this notice.	May 21, 2025 (August 31, 2020)
PSEHB/MDED Notification No. 0929-1 September 29, 202	Handling of Performance Evaluation Tests of Diagnostic Medical Devices Using Existing Medical Image Data without Involvement of Additional Invasiveness or Intervention EN/JP	In recent years, the practical application of diagnostic medical devices utilizing advanced technologies, such as medical imaging support systems that employ artificial intelligence technologies and gene mutation analysis systems that use DNA sequencers, has been progressing. This notification stipulates the handling of the performance evaluation test conducted by collecting existing medical image data or biological samples, as well as existing information on diagnosis and treatment related to them, without additional invasion/intervention for the purpose of using these data as an attachment to the marketing approval application form for such diagnostic medical devices.	May 21, 2025 (September 29, 2021)

Document Type & No.	Title	Summary	Posting Date (Issue Date)
PSEHB/MDED Notification No. 1117 (1) PSEHB/PSD Notification No. 1117 (1) November 17, 2017	Handling of Situations requiring submission of "Documents related to Clinical Study Results" for Medical Devices (Responses based on Measures across Pre-and Post-Marketing Phases) EN/JP	The scope for the submission of documents on clinical study results needed for marketing approval applications for medical devices have been shown in the "Scope of Required Clinical Study Data on Medical Devices" (PFSB/ELD/OMDE Notification No. 0804001, dated August 4, 2008 issued by the Director of Office of Medical Device Evaluation, Evaluation and Licensing Division, Pharmaceutical and Food Safety Bureau, Ministry of Health, Labour and Welfare) and the "Clarification of Handling of Clinical Trial Data on Medical Devices, etc. for Rare Diseases" (PFSB/ELD/OMDE Notification No. 0329-1 dated March 29, 2013 issued by the Director of Office of Medical Device Evaluation, Evaluation and Licensing Division, Pharmaceutical and Food Safety Bureau, Ministry of Health, Labour and Welfare). Because medical devices have characteristics such as frequent and diverse improvement, guidance related to clinical studies was examined to aimed to facilitate the more efficient development of medical devices while utilizing these characteristics. Based on the review conducted, we have organized the handling of cases in which approval applications may be considered regardless of whether new clinical trials are conducted before marketing by implementing safety and efficacy assurance measures consistently from the pre-marketing to the post-marketing phase. We have also clarified how these measures are implemented.	May 21, 2025 (November 17, 2017)
PSEHB/MDED Notification No. 0831-14 August 31, 2020	Handling Application for Confirming Change Plans for Medical Devices EN/JP	The Act for Partial Amendment of the Act on Securing Quality, Efficacy, and Safety of Products Including Pharmaceuticals and Medical Devices (Act No. 63 of 2019), promulgated on December 4, 2019, regarding the Act on Securing Quality, Efficacy, and Safety of Products Including Pharmaceuticals and Medical Devices (Act No. 135 of 1960), as amended by the aforementioned law, will come into effect on September 1, 2020. This notification stipulates the handling of the advanced notification system for confirmation of the change plan for medical devices, and changes in accordance with the plan.	May 21, 2025 (August 31, 2020)
Administrative Notice	Questions and Answers (Q&A) on the Application for Confirmation of Change Plans for Medical Devices, Medical Devices Utilizing Artificial Intelligence-Related Technologies, and Program Medical Devices EN/JP	The Regulatory Reform Implementation Plan approved by the Cabinet on June 16, 2023, stated that "from the viewpoint of improving the effects of the Change Plan Confirmation Procedure System (IDATEN), Q&A for necessary change plans should be enriched based on specific examples of formats and needs such as startups with little experience in development of medical devices." Based on this, we have integrated and partially revised the existing Q&A, and revised it as shown in the attachment.	May 21, 2025 (December 22, 2023)

Document Type & No.	Title	Summary	Posting Date (Issue Date)
PSB/MDED Notification No. 1116-2	Handling of the Two-step Approval Based on the Characteristics of Software as a Medical Device EN/JP	Handling of cases where it is considered possible to file an approval application for medical devices including software as medical device (SaMD), regardless of whether new clinical trials are conducted before marketing, is explained in "Handling on the Scope of Situations where "Documents related to Clinical Study Results" is Necessary on Medical Devices (Operations based on Measures through Pre-and Post-Marketing Phases)" (PSEHB/MDED Notification No. 1117-1 and PSEHB/PSD Notification No. 1117-1 issued jointly by the Director of Medical Device Evaluation Division, Pharmaceutical Safety and Environmental Health Bureau, Ministry of Health, Labour and Welfare and the Director of Pharmaceutical Safety Division, Pharmaceutical Safety and Environmental Health Bureau, Ministry of Health, Labour and Welfare, dated November 17, 2017). On this occasion, the ideal regulatory approval system, including the concept of two-step approval, was discussed from the viewpoint of efficient development and regulatory approval of SaMD, and "Publication of the Guidance for the Appropriate and Prompt Approval and Development based on the Characteristics of the Software as a Medical Device" (Administrative Notice of Medical Device Evaluation Division, Pharmaceutical Safety and Environmental Health Bureau, Ministry of Health, Labour and Welfare, dated May 29, 2023) was issued to clarify the handling and operationrelated to two-step approval based on the characteristics of SaMD as described below. Please note that the concept of two-step approval is an option and regulatory approval can be obtained without the application of this approach.	May 21, 2025 (November 16, 2023)
Administrative Notice	Q&A about "Handling of the Two-step Approval Based on the Characteristics of Software as a Medical Device" EN/JP	The concept of the two-step approval for software as a medical device (SaMD) is as described in the "Handling of the Two-step Approval Based on the Characteristics of Software as a Medical Device" (PSB/MDED Notification No. 1116-2 issued by the Director of Medical Device Evaluation Division, Pharmaceutical Safety Bureau, Ministry of Health, Labour and Welfare, dated November 16, 2023). On this occasion, we have compiled a list of questions and answers related to this notification as shown in the attachment.	May 21, 2025 (June 12, 2024)

Document Type & No.	Title	Summary	Posting Date (Issue Date)
Administrative Notice	Examples of Points to Consider and Approaches for Utilization of Study Results Obtained from Specified Clinical Research in Applications for Approval of Medical Devices and Regenerative Medical Products EN/JP	As one of the supplementary resolutions for the establishment of the Clinical Trials Act (Act No. 16 of 2017), it is stipulated that "clinical research should be promoted by clarifying regulatory classifications of clinical trials and clinical research and how they can be utilized, and a mechanism that enables the utilization of information obtained from clinical research for application materials for approval of drugs, medical devices, etc. should be considered promptly to promote the development of pharmaceuticals, medical devices, etc." In relation to this, the points to consider and approaches for pharmaceuticals are presented in "Examples of Points to Consider and Approaches for Utilization of Study Results Obtained from Specified Clinical Research in Applications for Approval of Pharmaceutical Products" (administrative notice of the Pharmaceutical Evaluation Division, Pharmaceutical Safety and Environmental Health Bureau, Ministry of Health, Labour and Welfare, dated March 31, 2023).	May 21, 2025 (June 5, 2024)
PSB/MDED Notification No. 0621-1 PSB/PSD Notification No. 0621-1	Partial Revision of "Partial Revision of the "Points to Consider for Approval Applications for Home Medical Devices to Detect Signs of Diseases and to Encourage Medical Consultation"" EN/JP	With the recent progress in various technologies, the advancement has been made in the development and commercialization of home medical devices including software as a medical device (SaMD) aimed at detecting signs of disease and encourage medical consultation. For this reason, consideration and specific countermeasures for the approval application of home medical devices that detect signs of disease and encourage medical consultation have been presented in "Partial Revision of the "Points to Consider for Approval Applications for Home Medical Devices to Detect Signs of Diseases and to Encourage Medical Consultation"" (PSEHB/MDED Notification No. 1213-4 and PSEHB/PSD Notification No. 1213-3 dated December 13, 2022 jointly issued by the Directors of the Medical Device Evaluation Division and the Pharmaceutical Safety Division, Pharmaceutical Safety and Environmental Health Bureau, Ministry of Health, Labour and Welfare). In view of the fact that multiple SaMD for home use have been developed to detect signs of diseases and encourage medical consultation, it was decided that the website of the Pharmaceuticals and Medical Devices Agency (PMDA) should be updated to provide a central summary of the list of medical devices for household use for detection of signs of diseases and encouraging medical consultation that have been approved in Japan as well as the information on the website of the marketing authorization holders to facilitate the obtaining of the latest information published by the marketing authorization by the users.	May 21, 2025 (June 21, 2024)

Document Type & No.	Title	Summary	Posting Date (Issue Date)
Administrative Notice	Complete Revision of "Revision of Basic Principles of Biological Safety Evaluation Required for Application for Market Approval of Medical Devices" EN/JP	This notification is the complete revision of "Revision of Basic Principles of Biological Safety Evaluation Required for Application for Market Approval of Medical Devices". And this document shows that marketing authorization holders of medical devices can refer to the methods, etc.	July 11, 2025 (March 11, 2025)

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